

CLAIMS

What is claimed is:

1. A method for producing and preserving a biopolymer scaffold material, comprising
5 the steps of:
 - a. harvesting tissue from an animal source;
 - b. optionally extracting growth and differentiation factors from said tissue;
 - c. inactivating infective agents of said tissue;
 - d. mechanically expressing undesirable components from said tissue;
 - 10 e. delipidizing said tissue;
 - f. washing said tissue for removal of chemical residues;
 - g. optionally drying said tissue; and
 - h. optionally cross-linking said tissue.
2. The method of claim 1 wherein said tissue is selected from the group consisting of
15 fetal, neo-natal and post-natal animal tissue.
3. The method of claim 2 wherein said tissue is bovine.
4. The method of claim 2 wherein said tissue is porcine.
5. A method for using the biopolymer scaffold material produced in claim 1 by applying
said biopolymer scaffold material to ^alesion or to damaged tissue to promote tissue
20 regeneration.
6. A method for using the biopolymer scaffold material produced in claim 1 as a cell
delivery, signaling complex or drug delivery device by
 - a. combining said biopolymer scaffold material with scaffolds made from naturally
occurring, man-made or self-degrading polymers, or with signaling complexes or
25 stem cells, or with drugs; wherein said signaling complexes ^{comprise said growth}
and differentiation factors extracted from said tissue ^{after said factors have been} and treated with sodium
hydroxide having a concentration consistent with the retention of biological
activity; and
 - b. applying said scaffold material and said scaffolds, signaling complexes, stem cells
30 or drugs to ^alesion or to damaged tissue to promote tissue regeneration.

7. A method for using the biopolymer scaffold material as in claim 5 for hernia-repair.
8. A method for using the biopolymer scaffold material as in claim 5 for colon, rectal, vaginal and/or urethral prolapse treatment.
9. A method for using the biopolymer scaffold material as in claim 5 for pelvic floor reconstruction.
10. A method for using the biopolymer scaffold material as in claim 5 for muscle flap reinforcement.
11. A method for using the biopolymer scaffold material produced as in claim 5 for supporting soft tissue of the lung.
- 10 12. A method for using the biopolymer scaffold material produced as in claim 5 for rotator cuff repair and/or replacement.
13. A method for using the biopolymer scaffold material produced as in claim 5 for periosteum replacement.
14. A method for using the biopolymer scaffold material produced as in claim 5 for dura repair.
- 15 15. A method for using the biopolymer scaffold material produced as in claim 5 for pericardial membrane repair.
16. A method for using the biopolymer scaffold material produced as in claim 5 for soft tissue augmentation.
- 20 17. A method for using the biopolymer scaffold material as in claim 5 for intervertebral disk repair.
18. A method for using the biopolymer scaffold material as in claim 5 for periodontal repair.
19. A method for using the biopolymer scaffold material as in claim 5 to provide a urethral sling.
- 25 20. A method for using the biopolymer scaffold material produced in claim 1 to provide a laminectomy barrier.
21. A method for using the biopolymer scaffold material produced in claim 6 to provide a spinal fusion device wherein said growth factors are rhBMP2 and said signaling complexes are bone signaling complexes.
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22. A method for producing and preserving a biopolymer scaffold material, comprising the steps of:

- a. harvesting a blood vessel from an animal source;
- b. optionally extracting growth and differentiation factors from said blood vessel;
- 5 c. inactivating infective agents of said blood vessel;
- d. delipidizing said blood vessel;
- e. washing said blood vessel for removal of chemical residues;
- f. optionally drying said blood vessel;
- g. optionally cross-linking said blood vessel; and
- 10 h. optionally terminally sterilizing said blood vessel;

23. The method of claim 22, further comprising returning said growth and differentiation factors to said blood vessel following said washing when said extracting is performed.

24. The method of claim 22, wherein said:

- 15 a. extracting comprises removing said growth and differentiation factors by an agent selected from the group consisting of buffer(s), enzyme(s) and acid(s).
- b. inactivating comprises immersing said tissue in bleach for between 1 minute and 5 hours, wherein said bleach is at a concentration of between 0.05% and 25%, and chilling said tissue in an ice bath at a temperature between -4°C and 10°C,
20 wherein salt is added to said ice bath to reach a temperature between 0°C and -4°C, and immersing said tissue in a solution of sodium hydroxide or potassium hydroxide for 10 minutes to 2 hours, wherein said solution is at a concentration of between 0.1 N and 10 N, and chilling said tissue in an ice bath at a temperature between -4°C to 10°C, wherein salt is added to said ice bath to reach a
25 temperature between 0°C and -4°C;
- c. delipidizing comprises immersing said tissue in a chloroform and ethanol solution (1:1 concentration) for between 5 minutes and 5 hours, and washing said tissue in 70% ethanol and water;

- d. terminally sterilizing comprises exposing said blood vessel to an agent selected from the group consisting of hydrogen peroxide, ethylene oxide and gamma radiation.
- e. drying comprises freeze-drying or air-drying said tissue; and
- 5 f. cross-linking comprises cross-linking said tissue with genipin or DHT.
25. A method for using the biopolymer scaffold material produced as in claim 22 by applying said biopolymer scaffold material to lesion or to damaged tissue to promote tissue regeneration.
26. A method for using said biopolymer scaffold material produced as in claim 22 as a
- 10 cell delivery, signaling complex^{delivered} or drug delivery device, comprising the steps of:
- a. combining said biopolymer scaffold material with scaffolds made from naturally occurring, man-made or self-degrading polymers, or with signaling molecules or
- 3 stem cells, or with drugs; wherein said signaling molecules comprise said growth and differentiation factors extracted from said blood vessel and treated with
- 15 sodium hydroxide having a concentration that is consistent with the retention of biological activity; and
- b. applying said scaffold material and said scaffolds, signaling complexes, stem cells or drugs to^a lesion or to damaged tissue to promote tissue regeneration.
27. The method of claim 22 wherein said animal source is chosen^{selected} from the group
- 20 consisting of fetal, neo-natal and post-natal.
28. The method of claim 22 wherein said animal source is chosen^{selected} from the group consisting of bovine and porcine.
29. A biopolymer scaffold material produced as in claim 22.
30. A cell delivery, signaling complex or drug delivery device as in claim 25.
- 25 31. The method of claim 25 wherein said signaling complexes attract endothelial precursor cells.